

Application Serial No. 09/988,013
Attorney Docket No. 40923-0048 US5

Remarks

In the Office Action mailed February 20, 2004, claims 25-27 were rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement, under 35 U.S.C. § 102, as being anticipated, and under 35 U.S.C. § 103, as being obvious. Claims 25-27 were rejected under the doctrine of obviousness-type double patenting over claims 1-4 of U.S. Patent No. 6,187,287 and over claims 1, 9, 20-21, 25-26 and 29-30 of U.S. Patent No. 5,789,554. The specific grounds for objection, and Applicants' response thereto are set out in detail below.

Claims 28-32 have been added. Support for steps (a), (b), (c), (d) and (e) of claim 28 can be found in the specification at paragraph [0043]. Additional support for step d of claim 28 can be found in the specification at paragraph [0067], last sentence. Support for claim 29 can be found in the specification at paragraphs [0043] and [0067]. Support for claim 30 can be found in the specification at paragraphs [0043] and [0067]. Support for claim 31 can be found in the specification at paragraph [0043], last sentence. Support for step (f) of claim 32 can be found in the specification at paragraph [0044], first sentence and Examples 2 and 3. Support for step (g) of claim 32 can be found in the specification at paragraphs [0044, 0045 and 0046]. Support for step (h) of claim 32 can be found in the specification at paragraph [0053]. Support for step (i) of claim 32 can be found in the specification at paragraph [0048].

In the Notice of September 3, 2004, the Examiner did not enter the amendments to the claims presented in the response filed August 20, 2004. Claims 28-32 were not entered for allegedly being directed to a different invention than the previously pending claims. Claims 28-32 are re-presented here and are designated as "not entered."

Claims 25-32 are pending for consideration, which is respectfully requested in view of the foregoing claim cancellations and additions, and the following remarks.

Rejection under § 112, first paragraph

Claims 25-27 are rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not enable the scope of the humanized LL2 antibodies and fragments claimed. Applicants respectfully traverse.

The enablement requirement of § 112, first paragraph requires only that the specification reasonably apprise those skilled in the art how to make and use the invention, and an application

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is presumed as a matter of law to be enabling. It is the Examiner's burden to overcome that presumption. The Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. In re Wright, 999 F.2d 1557, 1562 (Fed. Cir. 1993) (emphasis added). At a minimum, the examiner must give reasons for the uncertainty of the enablement. MPEP § 2164.04 (Rev. 1, Feb, 2003).

The MPEP further counsels that working examples are not per se required to satisfy the enablement requirement. See MPEP § 2164.02; see also Gould v. Quigg, 822 F.2d 1074, 1078 (Fed. Cir. 1987). The proper standard, instead, is whether the application teaches skilled workers in the field how to make and use the claimed invention in a manner that is commensurate with the scope of the claims. The applicants respectfully urge that applicants' specification meets this standard.

Applicants submit that one skilled in the art would readily be able to readily determine and generate the full scope of antibodies and fragments encompassed by the scope of claims 25-27 by employing no more than routine experimentation. Accordingly, withdrawal of the rejection respectfully is requested.

Rejection under § 102

Claims 25-27 are rejected under 35 U.S.C. § 102(b) as anticipated by Pawlak-Byczkowska et al., Goldenberg et al., Kreitman et al., Juweid et al., Goldenberg (US Patent 5,776,094) and two publications by Leung. Applicants respectfully traverse.

Applicants note that in order to reject a claim under 35 USC § 102, the examiner must demonstrate that each and every claim limitation is contained in a single prior art reference. *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986); *see also* MPEP § 2131 (August 2001). None of the cited references describe each and every element of the instantly claimed invention and therefore applicants respectfully request that the rejection under 35 USC § 102 be withdrawn.

In addition, Applicants submit that added claims 28-32 are not anticipated by any of the references cited by the Examiner. Specifically, the added claims are directed to the design and preparation of humanized antibody variable domains by combining antibody framework (FR)

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regions with the complementarity determining regions (CDRs) from a monoclonal antibody that is to be humanized, where at least two of the antibody FRs are from different human monoclonal antibodies. None of the cited describe the methods of claims 28-32. More specifically, none of references, either alone or in combination, suggest that humanized variable domains can be prepared that incorporate at least two antibody framework regions from different human monoclonal antibodies.

Rejection under § 103

The Examiner alleges that claims 25-27 are obvious under 35 U.S.C. § 103(a) over Pawlak-Byczkowska in view of Queen (U.S. Patent 5,530,101) and Orlandi. Applicants respectfully traverse.

All claims are presumed initially to be non-obvious. A *prima facie* case of obviousness requires three elements: (1) a teaching or suggestion of all of the claim limitations; (2) a suggestion or motivation to modify or combine the teachings of the applied prior art; and (3) a reasonable expectation of success in reaching the claimed invention. The Examiner bears the initial burden of supporting any *prima facie* assertion of obviousness with adequate facts. MPEP § 2142 (Feb. 2000).

Here, none of the cited references, either alone or in combination, disclose all the elements of claim 25 or added claim 28. Accordingly, the first element of a *prima facie* case of obviousness cannot be satisfied and withdrawal of the rejection respectfully is requested.

Rejections for Obviousness-Type Double Patenting

Claims 25-27 are rejected under the doctrine of obviousness-type double patenting over claims 1-4 of U.S. Patent No. 6,187,287 and over claims 1, 9, 20-21, 25-26 and 29-30 of U.S. Patent No. 5,789,554. Applicants respectfully request that this rejection be held in abeyance until an indication of allowable subject matter is received at which time an appropriate terminal disclaimer may be considered.

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CONCLUSION

In view of the above remarks and amendments, Applicants respectfully submit that this application is in condition for allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to telephone the undersigned at the number listed below if the Examiner believes such would be helpful in advancing the application to issue.

If any additional fees are required for the filing of this paper, Applicants authorize the Commissioner to charge any deficiency to Deposit Account No. 08-1641.

Respectfully submitted,

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By



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